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Registration Decision

Bifenazate

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Registration Decision for Bifenazate

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Bifenazate Technical (Registration Number 27923), Acramite 50 WS (Registration Number 27925) and Floramite SC (Registration Number 27924). Acramite 50 WS, containing the technical grade active ingredient bifenazate, is used to control European red mite, two-spotted spider mite and McDaniel mite (apples only) on apples and grapes, while Floramite SC is used to control two-spotted spider mite and Lewis mite on greenhouse ornamentals, including shadehouses and interiorscapes.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were proposed for conversion from conditional to full registration in the consultation document[1] Proposed Registration Decision PRD2009-11, *Bifenazate*. The detailed review of these products can be found in Regulatory Note REG2006-01, Bfenazate and PRD2009-11.This Registration Decision[2] describes this stage of the PMRA's regulatory process for bifenazate and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2009-11. This decision is consistent with the proposed registration decision stated in PRD2009-11.

For more details on the information presented in this Registration Decision, please refer to PRD2009-11 that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of the *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Bifenazate?

Bifenazate is the active ingredient in the end-use products Acramite 50 WS and Floramite SC. Acramite 50 WS is used to control European red mite, two-spotted spider mite and McDaniel mite (apples only) on apples and grapes, while Floramite SC is used to control two-spotted spider mite and Lewis mite on greenhouse ornamentals, including shadehouses and interiorscapes.

Health Considerations

Can Approved Uses of Bifenazate Affect Human Health?

Bifenazate is unlikely to affect your health when used according to label directions.

Potential exposure to bifenazate may occur through the diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive subpopulations in humans, such as children and nursing mothers.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose at which no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when bifenazate products are used according to label directions. The technical grade active ingredient bifenazate caused allergic skin reactions in animals. Consequently, the statement "Potential Dermal Sensitizer" is required on the label for the technical grade active ingredient.

Bifenazate did not cause cancer in animals and was not genotoxic. There was also no indication that bifenazate caused damage to the nervous system and there were no effects on reproduction. When bifenazate was given to pregnant animals, no effects on the developing fetus were observed at doses that were toxic to the mother, indicating that the fetus was not more sensitive to bifenazate than the adult animal. The primary health effects in animals given daily doses of bifenazate over longer periods of time were effects on blood cell formation and development. Additional effects included effects on the liver,

kidney, adrenals and mammary gland. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Residues in Water and Food

Aggregate dietary intake estimates (food plus water) revealed that the general population and infants, the subpopulation that would ingest the most bifenazate relative to body weight, are expected to be exposed to less than 26% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from bifenazate is not of concern for all population sub-groups. Bifenazate is not carcinogenic; therefore, a chronic cancer dietary risk assessment is not required.

Animal studies revealed no acute health effects. Consequently, a single dose of bifenazate is not likely to cause acute health effects in the general population, including infants and children.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout Canada and the United States using bifenazate on apples, grapes, greenhouse cucumbers, greenhouse pepper, greenhouse tomatoes, and strawberries were acceptable. The MRLs for this active ingredient can be found in the Science Evaluation of PRD2009-11.

Occupational Risks From Handling Acramite 50 WS and Floramite SC

Occupational risks are not of concern when Acramite 50 WS and Floramite SC are used according to label directions, which include protective measures.

Direct skin contact can occur when workers mix, load or apply either Acramite 50 WS or Floramite SC and when workers re-enter freshly treated fields, greenhouses, shadehouses and interiorscapes. Therefore, during mixing/loading or applying Acramite 50 WS or Floramite SC, and during clean-up and repair activities, workers must wear chemical resistant gloves, a long sleeved shirt, long pants, socks and shoes.

As a result of the evaluation of new data, risk to workers who re-enter treated fields was reassessed for all uses currently on the labels of Acramite 50 WS and Floramite SC. The personal protective measures on the labels were updated accordingly. Taking the updated label requirements into consideration, risk to workers handling product or exposed to areas freshly treated with Acramite 50 WS or Floramite SC is not of concern.

For bystanders, exposure is expected to be much less than for field workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Bifenazate Is Introduced Into the Environment?

Bifenazate and its transformation products are rapidly transformed in the environment and are non-persistent. They have a low potential for residue carryover. They also have a low potential to leach and contaminate groundwater. Bifenazate is moderately toxic to bees and the use of Acramite 50 WS will pose a risk to predatory and parasitic arthropods, and mammals on a dietary and reproductive basis. Bifenazate is highly toxic to freshwater and marine invertebrates and fish and the use of Acramite 50 WS may pose a risk to these organisms. Floramite SC will pose a risk to aquatic organisms if the greenhouse effluents are discharged into the aquatic systems. These risks have been mitigated by the addition of environmental hazard label statements.

Value Considerations

What Is the Value of Bifenazate?

Acramite 50 WS is used to control European red mite, two-spotted spider mite and McDaniel mite (apples only) on apples and grapes, while Floramite SC is used to control two-spotted spider mite and Lewis mite on greenhouse ornamentals, including shadehouses and interiorscapes.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being on the label of Acramite 50 WS and Floramite SC to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health
During mixing/loading or applying Acramite 50 WS or Floramite SC, and during clean-up and repair activities, workers must wear chemical resistant gloves, a long-sleeved shirt, long pants, shoes and socks.

After application of Acramite 50 WS, workers must not enter treated fields:

- For 5 days after application if cane turning and girdling grapes;
- For 1 day after application if hand harvesting, tying, pruning, training, leaf pulling, and hand thinning grapes; and
- For 12 hours after application if conducting other activities.

Workers must not enter treated fields for 12 hours after the application of Floramite SC.

Environment

The following label statements are required to minimize the potential risk to terrestrial and aquatic organisms with the use of Floramite SC and Acramite 50 WS:

***Floramite* SC**

- A statement is required to mitigate risk to aquatic organisms through discharge.

Acramite 50 WS

- Precautionary statements are required to mitigate risks to beneficial or parasitic arthropods and aquatic organisms.

Buffer zones of two or three metres are required, depending on the application method and use site.

Other Information

The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

References

A. List of Studies/Information Submitted by Registrant

1.0 Human and Animal Health

PMRA Document Number: 1117381
Reference: 2005, Acramite (UCC-D2341) 50WS on Apples: Dislodgeable Foliar Residue Study, RGC-99-R03; DNJ-99-110, DACO: 5.9

PMRA Document Number:1117382
Reference: 1999, Floramite 50WP on Staphiphyllum: Dislodgeable Foliar Residue Study, 98-150, MRID: 44859701,45052329, DACO: 5.9

PMRA Document Number: 1294460
Reference: 2006, Clarifications for Dislodgeable Foliar Residue Study of Floramite 50WP on Spathiphyllum, DACO: 5.9

PMRA Document Number: 1294466
Reference: 2006, Clarification for Dislodgeable Foliar Residue Study of Acramite 50WS on Apples, DACO: 5.9